



State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection

Ben Brancel, Secretary

DATE: October 29, 2014

TO: Board of Agriculture, Trade and Consumer Protection

FROM: Ben Brancel, Secretary
Steve Ingham, Administrator, Division of Food Safety

SUBJECT: ATCP 70 & 71 -Regulation of Food Warehouses, and affecting small business;
Rulemaking Scope Statement

PRESENTED BY: Steve Ingham, Division of Food Safety

REQUESTED ACTION:

At the November 19, 2014 Board meeting, the Department of Agriculture, Trade and Consumer Protection (DATCP) will ask the DATCP Board to approve a "scope statement" (copy attached) for potential changes to current DATCP rules related to food warehouses. Changes to be considered include: 1) exempting food warehouse operators from the requirement to obtain an additional food processing plant license for certain low-risk food processing activities conducted within a food warehouse, 2) harmonizing current food warehouse rules related to handling fish and fishery products, including molluscan shellfish, with federal regulations, state statutory requirements, and other existing state regulations, and 3) adding a requirement for food warehouse operators to develop and maintain a recall plan to provide adequate food traceability in emergencies.

Under state law, food warehouses (ch. ATCP 71) and food processing facilities (ch. ATCP 70) are distinct entities that require separate licensing. Current statute exempts food processing plants from also holding a food warehouse license (unless they are storing finished food products made elsewhere), but current rules would require a food warehouse operator seeking to perform low-risk packaging or re-packaging of foods to hold both licenses. This rule revision will examine whether minimal packaging and re-packaging of foods in a food warehouse should be exempt from food processing plant licensing.

Potential revisions could also modify food warehouse regulations to achieve consistency with federal and state regulations related to the storage of fish and fishery products, including molluscan shellfish. These fish and fishery products pose unique threats to human health, including histamine production in temperature-abused fish species such as tuna, and transmission of *Vibrio vulnificus* by molluscan shellfish. Existing federal and state regulations require that Wisconsin food warehouses handling molluscan shellfish for interstate commerce must hold a second (food processing plant) license. A possible revision may be to clarify this requirement in ch. ATCP 71, (Food Warehouses). Federal regulations treat the storage of fish and fishery products destined for wholesale as processing, and therefore subject to regulations mandating the implementation of the Hazard Analysis and Critical Control Point (HACCP) system. Wisconsin food processing plant regulations (ch. ATCP 70, Wis. Adm. Code) adopt, by reference, the federal HACCP regulations for fish processing done in a food

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processing plant, but do not apply the federal requirements for HACCP implementation to operators of warehouses which handle fish and fishery products. Potential revisions to amend this omission may entail adding a HACCP requirement for warehouse operators storing seafood to ch. ATCP 71, or clarifying that warehouse operators who store fish must hold a food processing plant license in addition to a food warehouse license.

Finally, as part of the rule revision, DFS will determine whether, and to what extent, ch. ATCP 71 should include written recall plan or record retention requirements in order to ensure adequate trace-back and trace-forward capabilities in response to an emergency such as an outbreak of foodborne illness. With the complexity of our food systems increasing, Wisconsin food warehouse operators routinely hold foods from multiple states and countries. Food emergency responses also routinely involve food originating several handlers and jurisdictions away. It is important that regulatory requirements facilitate rapid emergency response to these emergencies without unduly burdening warehouse operators.

A scope statement spells out the general purpose and scope of a proposed rule. DATCP may not begin drafting a proposed rule (including a proposal to amend or repeal an existing rule) until the Governor approves a scope statement for that rule as required under s. 227.135(2), Stats. This scope statement was approved by the Governor on September 22, 2014. Wisconsin statutes also require the DATCP Board to approve a scope statement before the department can begin to draft a proposed rule. DATCP is required to publish a draft scope statement in the Wisconsin Administrative Register, and file a copy with the Department of Administration (DOA), at least 10 days before the Board approves the scope statement. DATCP filed the attached scope statement with the Legislative Reference Bureau for publication in the October 14, 2014 issue of the Wisconsin Administrative Register and filed a copy with DOA as required.

Approval of a scope statement is just the first step in a lengthy rulemaking process. The Board will have at least two further opportunities to review the proposed rule. Before DATCP holds public hearings on this rule, the department must prepare an economic impact analysis and the Board must approve a hearing draft. The Board must also approve the final draft rule before DATCP may adopt the rule.

STATEMENT OF SCOPE

Department of Agriculture, Trade and Consumer Protection (DATCP)

Rule No.: Chs. ATP 71 and ATP 70, Wis. Adm. Code

Relating to: Food warehouses.

1. Description of the objective of the rule:

This proposed rule will modify current food warehouse rules to align with federal regulations, state statutory requirements, and existing state regulations. The proposed rule may also exempt food warehouse operators from obtaining an additional food processing plant license for certain food processing activities conducted within a food warehouse. These changes may include, but are not limited to, the following:

- Stating that a food warehouse operator must have a written recall plan and/or keep specified records that ensure adequate trace-back and trace-forward capabilities in response to an emergency such as an outbreak of foodborne illness.
- Clarifying that warehouse operators who, handle, receive, store, sort, shuck, repack, or otherwise process molluscan shellfish for interstate commerce must be licensed for these activities as a food processing plant under ch. ATP 70, Wis. Adm. Code.
- Clarifying that food warehouse operators storing fish or fishery products, including molluscan shellfish, must comply with the provisions of 21 CFR part 23 (Fish and Fishery Products). These federal regulations require implementation of the Hazard Analysis and Critical Control Point (HACCP) system by seafood processors. Federal regulations state that an establishment storing fish or fishery products is considered to be a processor subject to 21 CFR, part 123. Existing state regulations for food processing plants already require the implementation of HACCP, either by directly citing the federal regulations (s. ATP 70.18 (1), Wis. Adm. Code; for businesses processing fish for wholesale) or by explicitly stating the HACCP requirements (s. ATP 70.21 (18), Wis. Adm. Code; molluscan shellfish for interstate commerce).
- Stating that food warehouse operators licensed under ch. ATP 71, Wis. Adm. Code, may engage in limited packaging or repackaging of foods, other than molluscan shellfish, without obtaining a food processing plant license under ch. ATP 70, Wis. Adm. Code.

2. Description of existing policies relevant to the rule and of new policies proposed to be included in the rule and an analysis of policy alternatives; the history, background and justification for the proposed rule:

Under state regulations, facilities engaged in food processing must create and maintain food recall plans. In order to facilitate trace-back and trace-forward activities during the response to a recall or foodborne illness outbreak, it may be advantageous to require warehouse operators to likewise have written recall plans or other documentation.

Under state law, food warehouses and food processing facilities are distinct entities that require separate licensing, regulations (ch. ATCP 71 and 70, Wis. Adm. Code, respectively), and oversight. Wisconsin regulations do not generally consider food storage to be food processing. However, the storage of fish and fishery products, including molluscan shellfish, can pose unique threats to human health. Federal regulations treat storage of fish and fishery products, destined for wholesale, as processing and therefore subject to regulations mandating the implementation of the Hazard Analysis and Critical Control Point (HACCP) system. Wisconsin food processing plant regulations (ch. ATCP 70, Wis. Adm. Code) adopt, by reference, the federal HACCP regulations for fish processing done in a food processing plant, but are silent on the federal requirement for HACCP implementation by operators of warehouses which handle fish and fishery products. Wisconsin regulations also explicitly require implementation of HACCP for handling of molluscan shellfish which are involved in interstate commerce. These regulations (which are adapted from model federal guidance) also require the handling, receiving, storing sorting, shucking, repacking or other processing of molluscan shellfish for interstate commerce to be done in a licensed food processing plant. This existing requirement means that some Wisconsin food warehouses, specifically those handling molluscan shellfish for interstate commerce, must hold a second (food processing plant) licenses. The existing regulations for food warehouse operators are silent on this topic. Therefore, Wisconsin's regulations governing food warehouses must be revised to achieve clarity and consistency with the aforementioned existing federal and state regulations.

Under current rules, the minimal packaging and re-packaging of foods in an establishment, where the primary function is the storage of foods processed elsewhere, would also require a second (food processing plant) license. This additional license requirement may place an undue burden on businesses and the department should evaluate an exemption.

Confusion about regulatory and licensing requirements can impede the development of new food businesses. The department will evaluate the clarification of licensing requirements for firms storing fish and fishery products, including molluscan shellfish.

Policy Alternatives. Currently, ch. ATCP 71, Wis. Adm. Code, does not require food warehouse operators to create food recall plans. The existing regulations do, however, require food warehouse operators to keep records of each lot of food received and shipped from the warehouse. If the department does not alter the current rules, the lack of a recall plan, or more comprehensive records, at food warehouses could hinder food emergency response efforts by industry and regulators, thus increasing the risk of a public health hazard.

Without rule revision, there could still be confusion about whether federal seafood HACCP requirements are in effect. Fish and fishery product warehouses operating without HACCP plans would be in violation of federal law and could be increasing the risk of a food safety hazard if certain products are incorrectly stored.

If the department does not alter the current rules, state regulations would continue to require two licenses for food warehouse establishments performing only minimal packaging and re-packaging activities. The additional licensing cost may pose a sufficient economic burden to operators to discourage them from market participation. At the very least, additional licensing cost could be passed on to product consumers, making food products more expensive.

3. Statutory authority for the rule (including the statutory citation and language):

Statutory Authority: ss. 93.07 (1), 97.09 (4), 97.27 (5), and 97.29 (5) Stats.

93.07 Department duties. It shall be the duty of the department:

(1) REGULATIONS. To make and enforce such regulations, not inconsistent with law, as it may deem necessary for the exercise and discharge of all the powers and duties of the department, and to adopt such measures and make such regulations as are necessary and proper for the enforcement by the state of chs. 93 to 100, Stats., which regulations shall have the force of law.

97.09 Rules.

(4) The department may, by rule, establish and enforce standards governing the production, processing, packaging, labeling, transportation, storage, handling, display, sale, including retail sale, and distribution of foods that are needed to protect the public from the sale of adulterated or misbranded foods.

97.27 Food warehouses.

(5) RULE MAKING. The department may promulgate rules to establish the fees, required under sub. (3), or to govern the sanitary operation of food warehouses. Rules may include any of the following:

- (a) Standards for the construction and maintenance of food storage facilities.
- (b) Standards for the storage, identification and handling of food.
- (c) Record-keeping requirements to show the length of time that food is kept in storage.
- (d) Freezing and temperature requirements applicable to frozen-food warehouses, frozen-food locker plants and cold-storage warehouses.

97.29 Food processing plants.

(5) RULE MAKING. The department may promulgate rules to establish the fees, required under sub. (3) (a) or (c), or to govern the operation of food processing plants. Rules may include standards for the construction and maintenance of facilities; the design, installation, cleaning and maintenance of equipment and utensils; personnel sanitation; food handling and storage; sanitary production and processing; and food sources and food labeling.

4. Estimate of the amount of time that state employees will spend to develop the rule and of other resources necessary to develop the rule:

DATCP estimates that it will use approximately 0.05 FTE staff to develop this rule. That includes time required for investigation and analysis, rule drafting, preparing related documents, coordinating stakeholder meetings, holding public hearings and otherwise communicating with affected persons and groups. DATCP will use existing staff to develop this rule.

5. Description of all entities that may be impacted by the rule:

Warehouse operators who store fish and fishery products, but have not already implemented a HACCP system, would be most directly impacted because they would be required to develop and operate a HACCP system. Warehouse operators engaged in minimal food packaging or repackaging would be exempted from a requirement to purchase a second (food processing plant) license, unless they were engaging in storage or other specified activities with molluscan shellfish destined for interstate commerce. Warehouse operators would be required to create recall plans or keep specified records needed to facilitate trace-back and trace-forward activities during a food emergency. Consumers would benefit from more comprehensive HACCP requirements related to fish and fishery products, and improved effectiveness of food emergency response efforts.

6. Summary and preliminary comparison of any existing or proposed federal regulation that is intended to address the activities to be regulated by the rule:

Federal fish and fishery products regulations require processors of these foods to adopt HACCP systems. HACCP is an approach for preventing food safety hazards that involves identifying key food processing steps essential for ensuring safety. Processors must develop a plan to monitor and document that each of these key steps is functioning properly and minimizing food safety risks. As part of their HACCP plans, federally-inspected processors are required by 21 CFR 123 (c) (1) (ii) to identify preventive measures for food safety hazards that could arise from microbiological contamination. Microbiological contamination of stored product may occur if appropriate sanitary controls are not maintained.

Federal food inspection is divided between the USDA Food Safety Inspection Service (FSIS) and the Food and Drug Administration (FDA). The FSIS regulates meat and poultry production while the FDA regulates almost all other foods. Under 9 CFR 418, enforced by USDA, and a proposed rule by FDA, pursuant to the Food Safety Modernization Act (FSMA), regulated food facilities are required to create and maintain written food recall plans. Our proposed revisions are consistent with the federal rules and will help integrate federal and state food emergency response efforts.

The department's proposed rule revision will ensure Wisconsin's requirements are consistent with federal regulations and expectations for minimizing food safety hazards and food emergency response capability, while reducing the regulatory burden on some food warehouse operators.

7. Anticipated economic impact

This rule change will have a small economic impact on fish and fishery products warehouse operators and all other warehouse operators engaged in food processing as they will have to devote time and resources to developing HACCP systems, and food recall plans or related documentation. It is unlikely, however, that the additional cost will have a significant negative impact on business. Exemption from obtaining a separate food processing plant license in addition to a food warehouse license will help alleviate the economic burden.

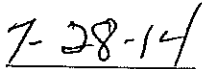
Contact Person: Steve Ingham, Division of Food Safety Administrator, DATCP; Phone (608) 224-4701



Ben Brancel

Secretary

Department of Agriculture, Trade and Consumer Protection



Date Signed

